LONG ISLAND SPINE SPECIALISTS, P.C
Jean-Jacques Abitbol, M.D.
Thomas J. Dowling, M.D.
Laurence E. Mermelstein, M.D.
Gerard D. D'Ariano, M.D.
Michael Osipoff, PA

December 6, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 97N-484S

To whom it may concern:

This is an official comment with regard to FDA proposal to regulate allograft as a medical device.

As you know, various types of musculoskeletal allografts including bone, ligament and tendon have been used for close to fifty years. They have made various procedures routine in this country not to mention reconstruction of severe ligament injuries, bone deficits and fusion of the spine.

The FDA already regulates the safety of the current bone bank, but if the FDA requires the bone banks to satisfy the FDA's pre-market requirements such as clinical trials, the countries position on the whole will suffer a significant shortage of allograft tissue which has become a routine part of my medical practice.

This proposal should be rejected and the use of allograft tissue would be regulated as is presently being done.

Very truly yours,

TJD/jr

Thomas J. Dowling, M.D.
COS #150404-2

d. allograft

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LONG ISLAND SPINE SPECIALISTS

2171 Jericho Turnpike, Suite 304

Commack, New York 11725

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Address Correction Requested